

REMARKS

Reconsideration of this application and the rejection of claims 1-11 and 14-16 are respectfully requested. Applicant has attempted to address every ground for rejection in the Office Action dated November 2, 2009 (Paper No. 20091008). The claims have been amended to more accurately describe the invention and Applicant believes the Application is now in condition for allowance.

Claims 1-11 and 14-16 stand rejected under 35 U.S.C. 112, second paragraph as being indefinite. As best understood, the Office Action alleges that these claims are indefinite because the product-by-process steps in claim 1 appear to yield an extract of rabbit skin, not a rabbit skin per se. Claims 1-11 and 14-16 have been amended so that they are now drawn to a rabbit skin extract instead of a rabbit skin. As such, Applicant submits that this rejection has been overcome. Claim 6, which was rejected for similar reasons, now recites "by injecting the rabbit subcutaneously". Applicant submits that the rejection of claim 6 has also been overcome. Claims 14 and 15 have been amended to clarify that the recited steps are substituted for the corresponding version of each step recited in claim 1. Therefore, Applicant submits that the rejection of claims 14 and 16 has been overcome.

Claims 1-11 and 14-16 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,057,324 to Shibayama et al. ("Shibayama"). Shibayama is cited for teaching a rabbit skin abstract that has inhibitory activity against kallikrein formation. Applicant respectfully submits that the presently claimed subject matter differs

substantially from Shibayama. Shibayama fails to teach, suggest, or disclose subject matter such as a rabbit skin having rabbit skin tissues possessing at least 0.5 iu/g SART activity.

Furthermore, the claimed rabbit skin extract has both the Kallikrein production inhibition and SART activity. Conversely, the substances in Shibayama have the Kallikrein production inhibition, but no SART activity. In addition and as asserted by Examiner, the resultant rabbit skin extract in the present claimed invention is related to the process. Shibayama describes a completely a different process that results in a completely different substance. The differences between the present claimed invention and Shibayama result in differences in the product. As we know, the performance of the bio-product is decided by the bio-active substances contained in it, and the bio-active substances contained in the bio-product are determined by the process for producing the bio-product.

As recited in amended claims 14 and 16, a portion of the rabbit skin is extracted with a phenol solution of 4 degrees Celsius, but in Shibayama the rabbit skin is extracted at room temperature. This distinction is very important and preserves the bio-activity of the bio-substances in the claimed rabbit skin abstract. Furthermore, as recited in claims 14 and 16, in the present invention the treatment in nitrogen is very important to protect the bio-active substances from oxidation. These contribute to the SART activity in the substance extracted from the rabbit skin as well as kallikrein production inhibition. Again, the substance in Shibayama has no SART activity.

Moreover, Shibayama explored ultra-filtration to remove a substance with a

molecular weight more than 20,000 or less than 1,000. The present invention only uses the filtration under a nitrogen atmosphere. Therefore, the quality and the quantity of the active substances are different, which also contributes to the high SART activity of the extracts. As such, the substances in the present invention are different in bio-activity from Shibayama because of the virus type, administration method and rabbit type are different.

The differences between Shibayama and the claimed invention can also be seen in the following table:

| Production Process | Shibayama | Present Claimed Invention |
|-----------------------|--|--|
| raw material | Infected tissue of rabbit | Infected tissue of rabbit |
| extracting conditions | Not mentioned | filtration and concentration steps were carried out under nitrogen atmosphere |
| | The active charcoal was used at room temperature, and the eluting temperature of the absorbed extraction from the active charcoal is 60°C. | The active charcoal was used at 30°C, and the eluting temperature of the absorbed extraction from the active charcoal is room temperature. |
| | Ultrafiltration, the substance which molecular weight is more than 20000 and less than 1000 was removed | Filtration |
| | Not mentioned. | The extraction are heated at 121°C for 20min, the resultant substance is stable at 121°C. |
| Resultant | A hygroscopic powder | The rabbit skin containing biologically active substances and the extracted solution |
| effect | Inhibitor of kallikrein formation | Kallikrein production inhibition and SART activity |

Accordingly, the Section 102 rejection is respectfully traversed for these reasons.

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Claims 1-11 and 14-16 also stand rejected under 35 U.S.C. §103, as being obvious in view of Shibayama. The arguments submitted above are reasserted here and the obviousness rejection of claims 1-11 and 14-16 is respectfully traversed.

In view of the above-identified amendments and remarks, Applicant respectfully submits that the claims in their present form are allowable over the issues raised in the Office Action mailed November 2, 2009. In the event that there are further issues which may be resolved by a telephone interview, the Examiner is urged to contact Applicant's undersigned Attorney at the telephone number listed below.

Respectfully submitted,

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